

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Fung *et al.* Confirmation No.: 4821
Application No.: 10/583,926 Art Unit: 1643
Patent No.: 7,674,459
Filed: December 23, 2004 Examiner: Yaen, Christopher H.
Issued: March 9, 2010
For: TREATMENT OF CANCER WITH NOVEL ANTI-IL13 MONOCLONAL ANTIBODIES Attorney Docket No: 12279-200-999

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER
37 C.F.R. § 1.705(d)**

MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The above-identified patent application, U.S. patent application no. 10/583,926 (hereinafter “the ‘926 application”), issued as U.S. patent no. 7,674,459 (hereinafter “the ‘459 patent”) on March 9, 2010. Patentee hereby respectfully requests reconsideration of the patent term adjustment indicated in the ‘459 patent. The ‘459 patent indicates a Patent Term Adjustment under 35 U.S.C. § 154(b) of 157 days. However, Patentee believes that the total patent term adjustment should be 456 days.

The present Request is filed within two months of the date the above-identified Patent issued, *i.e.*, before May 9, 2010, and thus is timely under 37 C.F.R. § 1.705(d).

The present Request raises an issue that could *not* have been raised under 37 C.F.R. § 1.705(b), because the issue relates to the patent issue date.

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(d) must be filed within two months of the date the patent issued and must comply with the requirements of 37 C.F.R. § 1.705(b), which are detailed below:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
(B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Patentee submits the following:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this request is believed to be **\$200.00**.

Please charge the required fee to Jones Day Deposit Account No. **50-3013**.

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.705(b)(2), Patentee submits the following statement of facts in support of this request:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 456 days, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '926 application fulfilled the requirements of 35 U.S.C. § 371 (delay of 211 days under 37 C.F.R. § 1.702(a)(1)); (b) the failure of the PTO to issue a patent within three years after the date on which the national stage commenced under 35 U.S.C. § 371(b) in an international application (delay of 259 days under 37 C.F.R. § 1.702(b)); and (c) reduction of period of adjustment of patent term under 37 C.F.R. § 1.704 (14 days).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

The total delay under 37 C.F.R. § 1.702 for adjustment of patent term under 37 C.F.R. § 1.702 is at least 470 days (the sum of 211 and 259 days).

(a) Delay under 37 C.F.R. § 1.702(a)(1)

The delay by the PTO under 37 C.F.R. § 1.702(a)(1) is 211 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date on which the '926 application fulfilled the requirements of 35 U.S.C. § 371. *See* PTO's Patent Application Information Retrieval page for U.S. Application No. 10/583,926, at Patent Term Adjustment History (Exhibit A). The '926 application fulfilled the requirements of 35 U.S.C. § 371 on June 20, 2007. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on March 19, 2009. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months from the date on which the '926 application fulfilled the requirements of 35 U.S.C. § 371 (or by August 20, 2008), and thus, the PTO delay under 37 C.F.R. § 1.702(a)(1) is 211 days, which is the period of time from August 20, 2008, to March 19, 2008. 37 C.F.R. § 1.702(a)(1).

(b) Delay under 37 C.F.R. § 1.702(b)

The delay by the PTO under 37 C.F.R. § 1.702(b) is 259 days.

The '926 application is a national stage of PCT International Patent Application No. PCT/US2004/043541, filed December 23, 2004, having a claimed priority date of December 23, 2003. Therefore, the national stage commenced under 35 U.S.C. § 371(b) on June 23, 2006 (*i.e.*, expiration of 30 months from the priority date). The '926 application issued as the '459 patent on March 9, 2010. Accordingly, the PTO failed to issue a patent within three years of the date on which the national stage commenced (*i.e.*, June 23, 2009), and thus, the term of the patent should have been adjusted because issuance was delayed by 259 days, which is the period of time from June 23, 2009, to March 9, 2010. 37 C.F.R. § 1.702(b). This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (*see* Exhibit A).

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” *See* 35 U.S.C. § 154(b)(2)(A).

According to 37 C.F.R. § 1.703(f): “The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not *overlapping*” (emphasis added). *See* 37 C.F.R. § 1.703(f).

Patentee respectfully submits that under controlling case law the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b) for the '926 application.

In *Wyeth et al. v. Kappos* (hereinafter *Wyeth*) the meaning of 35 U.S.C. § 154(b)(2)(A) was clarified. *See Wyeth v. Kappos*, 591 F.3d 1364 (Fed.Cir. 2010). In *Wyeth*, the court held that: “Before the three-year mark, no “overlap” can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect. If an A delay occurs on one day and a

B delay occurs on a different day, those two days do not ‘overlap’ under section 154(b)(2).” *Wyeth*, 591 F.3d at 1369-1370.

Turning to the ’926 application, the period of delay under 37 C.F.R. § 1.702(a)(1) occurred from August 20, 2008, fourteen months from the date on which the application fulfilled the requirements of 35 U.S.C. § 371, to March 19, 2009, the date on which a Restriction Requirement was mailed by the PTO. The period of delay under 37 C.F.R. § 1.702(b) occurred from June 23, 2009, three years from the date on which the national stage commenced under 35 U.S.C. § 371(b) in an international application, to March 9, 2010. Thus, the delay under 37 C.F.R. § 1.702(a)(1) (August 20, 2008 to March 19, 2009) occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b) (June 23, 2009 to March 9, 2010). Consequently, under 35 U.S.C. § 154(b)(2)(A), the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b) for the ’926 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a)(1) and 37 C.F.R. § 1.702(b), or at least **470** days (the sum of 211 and 259 days).

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.703(a)(1) for the period beginning August 20, 2008 (fourteen months after the date on which the ’926 application

fulfilled the requirements of 35 U.S.C. 371), and ending March 19, 2009, the date the Restriction Requirement was mailed from the PTO. Patentee confirms that this period consists of 211 days.

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued.”

Patentee submits that this period consists of 259 days, which is the period from June 23, 2009 (three years after June 23, 2006, *i.e.*, the date on which the national stage commenced under 35 U.S.C. 371(b)) to March 9, 2010 (the date a patent was issued). Patentee further submits that the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Patentee believes that the delays attributable to the PTO under 37 C.F.R. § 1.702 total 470 days (the sum of 211 and 259 days), not 211 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Patentee believes that the total delay by the PTO under 37 C.F.R. § 1.702(a)(1) and (b) amounts to 470 days. As discussed in section (iv) below, Patentee believes that the total delay attributable to Applicants under 37 C.F.R. § 1.704 amounts to 14 days. Patentee believes that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 456 days, which is the sum of the periods calculated by the PTO under 37 C.F.R. §§ 1.703(a) through (e) (*i.e.*, 470 days), to the extent that such periods are not overlapping, less the sum of the periods calculated under Section 1.704 (*i.e.*, 14 days).

- (iii) The '459 patent is not subject to a terminal disclaimer.

(iv) The circumstances during the prosecution of the '926 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the '926 application as set forth in 37 C.F.R. § 1.704 are believed to consist of the following:

1. a delay of 14 days by Patentee under 37 C.F.R. § 1.704(c)(10) due to Applicants' filing of other paper, *i.e.*, a Request for a Corrected Filing Receipt, after a notice of allowance has been given or mailed. Patentee submits that the PTO's determination of a delay of 54 days is incorrect.

37 C.F.R. § 1.704(c)(10) specifies that the period of adjustment set forth in section 1.703 shall be reduced by the lesser of: (i) the number of days, if any, beginning on the date the other paper was filed and ending on the mailing date of the notice in response to such other paper, or (ii) four months.

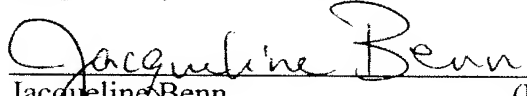
The Request for a Corrected Filing Receipt was filed on January 15, 2010, and a Corrected Filing Receipt, which is a notice in response to the Request for a Corrected Filing Receipt, was mailed on January 29, 2010. Therefore, the period of delay under 37 C.F.R. § 1.704(c)(10) is 14 days (January 15, 2010 to January 29, 2010), not 54 days as calculated by the PTO.

In summary, the total delays by the PTO under 37 C.F.R. § 1.702 is 470 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 is 14 days, and thus, the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 456 days. Accordingly, Patentees respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 456 days.

The PTO is invited to contact the undersigned regarding any questions concerning any of the above.

Respectfully submitted,

Date: May 5, 2010


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